IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant:	Mason	Atty Dkt:	2731/101
Serial No:	09/976,685	Art Unit:	3732
Date Filed:	October 11, 2001	Examiner:	D. A. Bonderer

Invention: Graftless Spinal Fusion Device

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CERTIFICATE OF MAILING

I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on May 29, 2003.

John L. Conway

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Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

DECLARATION IN SUPPORT OF APPLICANT'S RESPONSE
[37 C.F.R. Section 1.132]

The undersigned Michael Mason does hereby declare as follows:

1. My name is Michael Mason and I am the inventor of the invention disclosed in the above-referenced application. I have been awarded the following degrees: Doctor of Osteopathic Medicine, Philadelphia College of Osteopathic Medicine, 1987; Bachelor of Science, Chemistry and Biology, West Chester University, 1983, *magna cum laude*. I am a licensed medical doctor in the Commonwealths of Massachusetts and Pennsylvania. I am board certified in Orthopedic Surgery and have practiced in this field for over 10 years. I have also

designed four orthopedic devices. These devices are currently approved and manufactured worldwide. I consider myself skilled in the art of orthopedic device design. The attached curriculum vitae provides further details on my background.

2. I have reviewed the office action mailed on December 31, 2002 and the cited references: Hirayama et al., "Artificial Intervertebral Disc," U.S. Pat ser. no. 4,946,378 and Ferree, "Artificial Intervertebral Disc Replacement Methods and Apparatus," U.S. Pat. ser. no. 6,419,704.

3. Hirayama's implant is a replacement for a disc. The implant separates and cushions the adjacent vertebrae. This implant is meant to maintain motion between these vertebrae. In contrast, my implant is for spinal fusion which eliminates relative motion of adjacent vertebrae. Hirayama's implant cannot be used for spinal fusion since it lacks the required rigidity.

4. Ferree teaches an artificial replacement for intervertebral discs. This replacement makes use of a shaped body having a final volume sized to consume at least a portion of an intervertebral disc space, and a filling within the shaped body enabling the body to cyclically compress and expand in a manner similar to the disc material being replaced. The filling may be a gas, liquid or a gel. Like the Hirayama device, the Ferree device is unsuitable for fusing vertebrae since the device does not provide the rigidity required, i.e., the device does not provide the response to sheer or tensile stress needed to immobilize the vertebrae.

5. The implant devices I invented are superior to prior art intervertebral fusion devices that require a bone graft. Embodiments of my invention include members protruding from an implant body. The members and associated body surfaces may be coated with a bioactive coating. This bioactive coating allows these members to rapidly attach to keyways formed in the corresponding vertebrae. The relatively rigid materials that may comprise the implant body (such as titanium steel in one version) effectively immobilize the adjacent vertebrae after insertion, achieving fusion without the use of a bone graft.

6. In inventing implants and the associated methods for spinal fusion, I realized that the shape and placement of the protruding members of the implant were important for enhancing bonding of the implant to the vertebrae. First, an empirical formula for what I call "fixation" of the member into the vertebra was developed. Fixation is the degree to which the protruding member bonds to the vertebral bone. The greater the fixation, the more stress the bond can take. The extent of fixation is equal to the surface area of the member times the density of the bone to which the member is bonded. For example, a horseshoe-shaped protruding member, with its convex profile, provides more surface area than a dovetail-shaped member and should provide better bone fixation.

7. Secondly, cortical bone, which is at the periphery of a bone, is denser than bone at the center of a bone and embodiments of the present invention take advantage of this configuration. In one embodiment of my

invention, we provide two members on an implant surface, positioned away from the center of the surface, so that each of the members is anchored in the denser bone near the outside of a vertebra. This placement of members enhances fixation.

8. Thirdly, since bone formation will increase in areas subjected to compression according to Wolff's Law, a horseshoe-shaped protruding member should facilitate growth of denser bone near points where the protruding member meets the body of the implant. This follows since bone in this area is subjected to a higher level of compression than is the case for a dove-tail shaped member: the dovetail "shadows" the developing bone in this area from compressive stresses that are passed along for the horseshoe-shaped protruding member. Thus, fixation of the implant in the vertebrae is further enhanced. The effect of the shape of a protruding member on vertebral fixation for the implant, when inserted, is not obvious. It is not a simple matter of design choice.

9. I further state that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements are made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

Michael Mason, D.O.

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EDUCATION

COLLEGE: West Chester University, 1983
Bachelor of Science, Chemistry and Biology
Magna Cum Laude

MEDICAL SCHOOL: Philadelphia College of Osteopathic Medicine
Doctor of Osteopathic Medicine, 1987

TRAINING

INTERNSHIP:
7/87 – 6/88
Rotating Internship
Community General Hospital
Harrisburg, PA

RESIDENCY:
7/88 – 6/92
Orthopaedic Surgery
Community General Hospital
Harrisburg, PA

Visiting Resident
Harvard Combined Orthopaedic Residency Program
Boston, MA

FELLOWSHIP:
8/92 – 7/93
Adult Reconstruction
Harvard Medical School
Brigham & Women's Hospital
Boston, MA

CERTIFICATION and LICENSURE

BOARD CERTIFIED: American Osteopathic Board of Orthopedic Surgeons, 1996

DIPLOMATE: National Board of Medical Examiners, 1988

MEDICAL LICENSURE: Massachusetts, (80434)
Pennsylvania, (OS 006572L)

MILITARY SERVICE

UNITED STATES ARMY: Presidential White House Honor Guard, 1975, 1976
Washington, D.C.

ACADEMIC APPOINTMENTS

Boston University School of Medicine: Boston, MA
Assistant Professor in Orthopaedic Surgery
April 1994 - Present

Harvard Medical School: Boston, MA
Clinical Instructor In Orthopaedic Surgery
August 1993 – Present

Harvard Medical School: Boston, MA
Clinical Fellow In Orthopaedic Adult Reconstruction
August 1992 – July 1993

PROFESSIONAL EXPERIENCE

Boston University School of Medicine: Boston, MA
Assistant Professor in Orthopaedic Surgery, 4/94 - Present
University Hospital
Boston City Hospital

Howmedica Osteonics: Allendale, NJ
Consultant, 1994 - Present

Harvard Medical School: Boston, MA
Clinical Instructor In Orthopaedic Surgery, 8/93 – 3/94
Massachusetts General Orthopedic Associates
The Cambridge Hospital

Harvard Medical School: Boston, MA
Clinical Fellow In Orthopaedic Adult Reconstruction, 8/92 – 7/93
Brigham and Women's Hospital

Community General Hospital:
Chief Surgical Resident, 7/91 – 6/92

PROFESSIONAL ORGANIZATIONS

American Osteopathic Academy of Orthopaedic Surgeons

American College of Osteopathic Surgeons

Massachusetts Medical Society

Massachusetts Osteopathic Society
Treasurer, Board of Directors

American Osteopathic Association

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PUBLICATIONS

Total Elbow System Surgical Protocol
Inglis AE, Bonutti PM, Rosenberg G, Coleman DA, Mason MD
Solar Upper Extremity System
Stryker Howmedica Osteonics

Total Shoulder System Surgical Protocol
RH Bell, Bonutti PM, Morris HB, Mason MD, Naylor P, Rosenberg G
Solar Upper Extremity System
Stryker Howmedica Osteonics

Total Elbow System Surgical Protocol
Ford M, Hall H, Mason MD, Nash C, Stephens C, Vaughan JJ, Armstrong D, Lapresle P, Missenard G
Osteonics Spinal System
Posterior System Surgical Protocol
Osteonics Corporation

The Effect of Component Design on the Performance of Glenoid Prostheses
Orr TE, Wong, BE, Mason, MD
Journal of Shoulder and Elbow Surgery
In Press

Kinematic Total Knee Arthroplasty: A Ten to Fourteen Year Prospective Follow-Up Review
Ewald FC, Wright RJ, Poss R, Thomas WH, Mason MD and Sledge CB
Journal of Arthroplasty
June 1999

Assessment of Neuroforaminal Decompression in Degenerative Spinal Stenosis
Gill TJ, Mason MD
Clinical Orthopaedics and Related Research
March 1998

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Eustace S, Yucel EK, Melhem, Mason M, Goldberg Right
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A Comparison of Conventional Spine-Echo and Turbo Spin Echo Sequences in the Imaging of Orthopaedic Hardware
Eustace S, Jara H, Goldberg R, Fenlon H, Mason M, Melhen ER, Yucel EK
American Journal of Radiology
February 1998

Rice Body Formation in Bicipito-Radial Bursitis: Ultrasound, CT and MRI Findings
Spence LD, Adams J, Gibbons D, Mason MD and Eustace S
Skeletal Radiology
January 1998

Current Imaging of Orthopaedic Hardware
Eustace S, Mason MD
Orthopaedic Clinics of North America
January 1998

Imaging Orthopedic Hardware with an Emphasis on Hip Prostheses.
Eustace S, Shah B, Mason M
Orthopedic Clinics of North America
January 1998

Ten to Fourteen Year Review of a Non-Constrained Cruciate Retaining Condylar Total Knee Arthroplasty
Orthopaedic Transactions
J Bone and Joint Surgery
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Three Pegged All Polyethylene Resurfacing Patellae: Two to Six Year Results
Mason MD, Brick GW, Scott RD and Ewald FE
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J Bone and Joint Surgery
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Chronic Complicated Osteomyelitis of the Lower Extremity: Evaluation With MR Imaging
Mason MD, Zlatkin MJ, Esterhai JL, Dalinka MK and Kressel HY
Radiology 1989; 173: 355 - 359

The Formation of the Gray Crescent in the Unactivated Egg of Rana pipiens
Zimmerman ID and Mason MD
American Zoologist 1983; 23: 4

PRESENTATIONS

Quantification of Pedicle Screw Toggle Movements During Cyclic Bending Loads: Conical vs. Cylindrical Pedicle Screws
Jensen L, Szirtes B, Mason M, Nolte L, Orr The
Orthopedic Research Society
Poster Exhibit
Orlando, 2000

Factors Affecting Prosthetic Design in TSR and Complications of TS: Recognition and Treatment
State of the Art in Orthopaedics 2000
Whistler, British Columbia, 2000

The Effect of Implant Design on the Stability of Glenoid Components
American Academy of Orthopaedic Surgeons 64th Annual Meeting
Poster Exhibit
San Francisco, 1997

The Effect of Component Fixation Design on the Performance of Glenoid Prostheses
Orr TE, Wong BE, Maw K, Ashmore WP, Mason MD
Orthopedic Research Society 43rd Annual Meeting
San Francisco, 1997

MR Imaging of Orthopaedic Hardware: Techniques to Reduce Susceptibility Artifact
Goldberg R, Jara H, Mason MD, Yucel EK, Eustace S
Radiological Society of North America
Chicago, 1996

The Elbow: The Forgotten Joint
American Osteopathic Academy of Orthopaedics Annual Meeting
Dearborn, 1996

The Space Available for the Nerve Root in the Senescent Lumbar Spine
Mason MD, Gill T
American Academy of Orthopaedic Surgeons 63rd Annual Meeting
Poster Exhibit
1996

MR Imaging of Orthopaedic Hardware: Techniques to Reduce Susceptibility Artifact
Goldberg R, Jara H, Mason MD, Yucel EK, Eustace S
American Radiology Society
San Diego, 1995

Intra-operative Assessment of Neuroforaminal Decompression in Spinal Stenosis Surgery
Mason MD, and Gill TE
Scientific Program Presentation
American-European Meeting on Pedicle Fixation of The Spine and Other
Advanced Techniques
Munich, Germany
July, 1994

Examination of Regional Bone Densities Within the Glenoid Vault: Influence on Component Design and Stability
Mason MD, Kalus RM, Thornhill TS and Cheal EJ
Scientific Program Presentation
Orthopaedic Research Society
New Orleans, Louisiana
February, 1994

Ten to Fourteen Year Review of a Non-Constrained Cruciate Retaining Condylar Total Knee Arthroplasty
Mason MD, Ewald FE, Sledge CB and Wright JR
Scientific Program Presentation
American Academy of Orthopaedic Surgeons
San Francisco, 1993

Three Pegged All Polyethylene Resurfacing Patellae: Two to Six Year Results
Mason MD, Brick GW, Scott Rd and Ewald FE
Scientific Program Presentation
American Academy of Orthopaedic Surgeons
San Francisco, 1993

Proximal Femoral Allografts in Revision Total Hip Arthroplasty; Surgical Technique and Results
Mason MD, Vaneenaman P and Brick EW
Scientific Program Presentation
Pennsylvania Orthopaedic Society
Bermuda, 1993

Evaluation of Chronic Complicated Osteomyelitis: A Comparison of MRI and Indium-111 Scanning
Mason MD and Zlatkin MJ
Scientific Program Presentation
Roentgenological Society of North America
Chicago, 1988